

**REMARKS**

**A. BACKGROUND**

The present Amendment is in response to the Office Action mailed February 19, 2010. Claims 1-3, 5, 6, 9, 11, 12, 15, 16, and 21-28 were pending and rejected in view of cited art. Claims 1-3, 9, and 23-24 are amended. Claims 1-3, 5, 6, 9, 11, 12, 15, 16, and 21-28 remain pending in view of the above amendments, with claims 1 and 23 being independent.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

**B. PRIOR ART REJECTIONS**

**I. REJECTION UNDER 35 U.S.C. § 103**

As noted by the Applicant in their specification, the invention is directed to a method of trimming a balloon of a balloon catheter and associated construction of the balloon catheter in accordance with the method. As presented herein for reconsideration (see independent claim 1 as exemplary), the invention claimed in independent claim 1 generally comprises forming a tube of balloon material into a balloon shape to form a balloon. The method further includes folding the balloon and then, outside of a mold, creating protrusions on the folded balloon by wrapping a member around the balloon such that spaced-apart loops of the member wrapped around the balloon compress the balloon leaving uncompressed portions of the balloon between the spaced apart loops of the member wrapped around the balloon to form the protrusions on the balloon. With the folded balloon and the member outside of the mold, leaving the member wrapped around the balloon for a predetermined period of time and removing the member from the balloon after the predetermined period of time. Further, following removal of the member from the balloon and forming of the protrusions on the balloon, positioning a stent defining a plurality

of apertures around the balloon such that the protrusions extend through the plurality of apertures defined by the stent.<sup>1</sup>

The Office Action rejected claims 1-3, 5, 6, 9, 11, 12, 15, 16, and 21-28 under 35 U.S.C. § 103(a) as being unpatentable over European Patent No. 1132059 (*Johnson*) in view of U.S. Patent No. 5,295,959 (*Gurbel*), U.S. Patent No. 6,161,209 (*Spreigl*), U.S. Patent No. 6,238,430 (*Klumb*), U.S. Patent No. 5,242,451 (*Harada*), U.S. Patent No. 4,886,062 (*Wiktor*), U.S. Patent No. 5,308,356 (*Blackshear Jr.*), and optionally U.S. Patent No. 5,352,199 (*Tower*).

Applicant respectfully submits that the independent claims as presented for reconsideration are not anticipated nor made obvious by Johnson either singly or in combination with any other reference of record.<sup>2</sup> *Johnson* discloses a balloon catheter with balloon shoulders (Title). As described in *Johnson*, “[t]he balloon is folded into any suitable or preferable number of longitudinal pleats which are wrapped around a portion of the catheter shaft” (Para. 0031). “[A] stent is slipped onto the pleated balloon . . . [and] then gently crimped or compressed around the balloon” (Para. 0032). “[T]he resultant balloon catheter and stent assembly is then placed in a tubular mold” (Para. 0033). “The balloon is then pressurized by applying a pressurized fluid to the inflation port” and “the mold with accompanying balloon catheter and stent assembly . . . are held in a hot box or heated die” (Para. 0035 and 0036). In another configuration, a “phantom stent” replaces the “stent” and the balloon is formed using the “phantom stent,” which is subsequently removed following balloon formation.

As indicated in the Office Action, “although the protrusion-forming step of Johnson is disclosed as being performed in a mold, the protrusions are formed into a pre-formed balloon. It is necessary for this balloon to be formed some how” and “Blackshear . . . show[s] that one of ordinary skill would find it obvious to make this balloon [i.e., the pre-formed balloon] by molding” (Office Action, pp. 7 and 8). From this discussion, Applicant understands that *Johnson* and *Blackshear* were combined to teach that invention claimed in the previous amendment that

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<sup>1</sup> The other independent claim (e.g. claim 23) is similar.

Claim 23 differs from claim 1, for example, by adding the further limitation of “outside of a mold, creating protrusions along the length of the folded balloon by wrapping a member around the balloon such that spaced-apart loops of the member wrapped around the balloon compress the balloon leaving uncompressed portions of the balloon between the spaced apart loops of the member wrapped around and along the length of the balloon to form the protrusions on the balloon” and “attaching the balloon to a balloon catheter.” Claim 23 should also be allowed for the same reasons as claim 1, since claim 27 merely adds further limitations to those recited in claim 1.

<sup>2</sup> Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

included "introducing a tube of balloon material into a balloon forming mold; forming a tube of balloon material into the balloon shape; removing the balloon from the mold; following folding the balloon after removing the balloon from the mold . . ."

To clarify the method, independent claim 1 has been amended to recite, in part, "forming a tube of balloon material into a balloon shape to form a balloon; folding the balloon; outside of a mold, creating protrusions on the folded balloon by wrapping a member around the balloon . . . ; with the folded balloon and the member outside of the mold, leaving the member wrapped around the balloon for a predetermined period of time" (emphasis added). As mentioned above, *Johnson* neither teaches nor suggests such method because the protrusions of *Johnson* are formed in a mold. Even if, *arguendo*, *Blackshear* were combined with *Johnson* to teach the forming of the pre-formed balloon, the combination of *Blackshear* and *Johnson* would still not teach or suggest the invention claimed in independent claims 1 and 23 because *Blackshear* neither teaches nor suggests "outside of a mold, creating protrusions on the folded balloon by wrapping a member around the balloon . . . ; with the folded balloon and the member outside of the mold, leaving the member wrapped around the balloon for a predetermined period of time" (emphasis added).<sup>3</sup>

Accordingly, for at least the reasons noted<sup>4</sup>, independent claims 1 and 23 and the claims depending therefrom<sup>5</sup> are neither anticipated nor made obvious by *Johnson*, either singly or in combination with any other cited prior art of record<sup>6</sup>, and thus reconsideration and withdrawal of the rejection is respectfully requested.

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<sup>3</sup> For the same reasons stated above, combining the teaching of *Gurbel* with *Johnson* and/or *Blackshear* also fails to teach or suggest "outside of a mold, creating protrusions on the folded balloon by wrapping a member around the balloon . . . ; with the folded balloon and the member outside of the mold, leaving the member wrapped around the balloon for a predetermined period of time" because the Office Action indicates that *Gurbel* suggests "that recesses [that match the coils of a stent] are created with the use of a wrapped phantom stent during the molding step" (Office Action, p. 4)(emphasis added).

<sup>4</sup> Likewise, *Johnson* also clearly does not disclose a catheter balloon that includes in combination (1) creating protrusions along the length of the folded balloon, outside of a mold, and (2) "with the folded balloon and the member outside of a mold, leaving the member wrapped around the balloon for a predetermined period of time" (emphasis added). Thus, claim 23 is also patentable over *Johnson* for this reason as well.

<sup>5</sup> Emphasis herein of the differences between the independent claims and the prior art are equally applicable to the dependent claims 2-3, 5, 6, 9, 11, 12, 15, 16, 21, 22, and 24-28, but this does not mean, on the other hand, that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicants thus do not acquiesce in any asserted rejections of the dependent claims 2-3, 5, 6, 9, 11, 12, 15, 16, 21, 22, and 24-28.

<sup>6</sup> *Gurbel*, *Spreigl*, *Klumb*, *Harada*, *Wiktor*, *Blackshear*, and *Tower* were cited as secondary references. Discussion of *Gurbel* and *Blackshear* were provided previously, including footnote 3. Although *Tower* was cited as being "optionally" combinable with *Johnson*, no discussion was presented in the Office Action. *Spreigl*, *Klumb*, *Harada*, and *Wiktor* were cited for that proposition that they each disclose "use of stents with a plurality of apertures between adjacently spaced loops in the stents" (Office Action,

C. **CONCLUSION**

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 18<sup>th</sup> day of June, 2010.

Respectfully submitted,

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p. 3). *Harada* was also cited for the proposition that it discloses a "stent has a flat-band shape," *Spreigl* was also cited for the proposition that it discloses "a catheter with a thread-like cross-section" and *Klumb* was cited for the proposition that they disclose "a thread-like stent" (Office Action, pp. 6 and 7). That said, none of these references otherwise add anything in terms of reading on the claims as amended herein, particularly in reference to those claimed limitations noted above which clearly define over *Johnson*. Thus, even assuming *arguendo* that any of the references to *Gurbel*, *Spreigl*, *Klumb*, *Harada*, *Wiktor*, *Blackshear*, and *Tower* are properly combinable with *Johnson*, such combinations are clearly distinguished by the claims for the reasons already noted in reference to *Johnson*.